REMARKS

Reconsideration of this application is requested in view of the amendments to the claims and the remarks presented herein and the petition submitted to the Commissioner filed herewith.

The claims in the application are claims 1 to 14, 17 and 18, all other claims having been cancelled. With respect to the Examiner's objection in paragraph 4, the sentence "What We Claim Is" has been inserted before the claims and therefore, this is deemed to obviate this objection.

In paragraphs 1 to 5, the Examiner rejected claims 1 to 3 and 13 under 35 USC 101 as being directed to non-statutory subject matter. The Examiner was of the opinion that they did not distinguish over naturally occurring nucleic acids and cells. The Examiner has suggested that the claims be amended to indicate the hand of the inventor which the present claims do by using the term "recombinant DNA". Therefore, it is deemed that this rejection is obviated.

Claims 1 to 3, 12, 13, 17 and 18 were rejected under 35 USC 101 since the Examiner was of the opinion that the claims were not supported by a specific asserted utility or a well established utility. The Examiner was of the opinion that the specification nor any art of record would not teach the specific role of hTFIIIA in the

course of a disease such as cancer and the statement in the specification that the gene "probably play an important role in the initiation of the transcription of the 5S ribosomal RNA gene, and in maintaining the stability of the transcription of other genes involved in the control function". Page 15, in the Examiner's opinion, indicates that the function of hTFIIIA has not been clearly delineated.

Applicants respectfully traverse this ground of rejection since it is believed that the claims encompass recombinant DNA which is clearly useful. As stated on page 14, line 36 through line 2 of page 15 of the application, hTFIIIA is useful as a transcription regulation factor. This is explained by Moorefield B et al (J. Biol.Chem.) cited by the Examiner which states "human TFIIIA is of special interest from the stand point of reconstructing a completely homogeneous cell free transcription system" (see page 20857, the third paragraph of column 2). Moorefield B et al presents the purification of Human transcription factor IIIA from HeLa cells but does not present recombinant DNA. It is well known the biochemical purifications of proteins still carry some contaminates. Recombinant DNAs of the present invention are useful as they permit one to obtain recombinant proteins that have a greater level of purity compared to extracted proteins. The production of recombinant proteins is also less expensive and the yield is higher compared to purification. The expression vectors and host cells of claims 12 and 13 are also useful.

Another utility of the present invention concerns the field of cancer and as set forth on page 15, some regulation factors have been implicated in cancer. Applicants are submitting herewith a copy of an article by Tanabe et al showing a link between TFIIIA and cancer. TFIIIA, which is expressed at high levels in the liver, is implicated in the up regulation of Glutathione transferase P during chemical hepatocarcinogenesis and as explained in the article, Glutathione transferase P is an excellent tumor marker. The fact that TFIII may bind to the promoter of this gene has been demonstrated in the article and suggests a binding and regulation of this important gene in hepatocarcinoma by TFIIIA. Therefore, it is believed that the application clearly has a utility for the claimed invention and withdrawal of this ground of rejection is requested.

Claims 17 and 18 were rejected under 35 USC 112, first paragraph, as failing to be based upon an enabling disclosure. The Examiner states that the subject matter claimed is not described in the specification so as to enable one skilled in the art to make or use the invention since the claims are drawn to a method of treating a disease linked to transcriptional control disorders wherein the disease may be cancer. The Examiner deems that this is improper since the art teaches that cancer is a rather unpredictable and difficult disease to treat and the specification does not specifically teach the addition or elimination of hTFIIIA from cells and the effect such a process would have on the progression of a specific disease.

Applicants respectfully traverse this ground of rejection since it is believed that claims 17 and 18 are based upon an enabling disclosure and would teach one skilled in the art how to use the same. Applicants call the Patent Office's attention to the Tanabe et al reference which teaches that TFIIIA, which is expressed at a high level in the liver, is implication in the up regulation of Glutathione transferase P during chemical hepatocarcinogenesis and therefore, it is deemed that one skilled in the art would be taught that the claimed method is useful.

Claim 1 was rejected under 35 USC 102 as being anticipated by the Seifart et al refernce or the Moorefield B et al reference. The cancellation of claim 1 obviates these grounds of rejection.

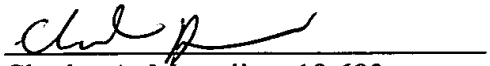
Claims 1 to 3 were rejected under 35 USC 103 as being anticipated by the Arakawa et al reference.

Claims 1 to 3, 12 and 13 were rejected under 35 USC 102(f) because the Examiner is of the opinion that the Applicant did not invent the claimed subject matter. The Examiner states that the present claims are drawn to a DNA sequence of hTFIIIA and that the said DNA sequence is claimed in EP '526 application wherein the identity between the two sequences is 99.4%. The Examiner is of the opinion that the claimed sequence is derived from the 356 sequence and therefore, the instantly claimed sequence is derived from that of the '526 reference.

Applicants respectfully traverse this ground of rejection since it is believed that Applicants are the inventors of the present invention and Applicants do not understand the Examiner's reason for the rejection. The Examiner explained that the identity between the sequences disclosed by the reference and that of the present invention is high and therefore, the sequences are "derived from the '356 reference". Applicants believe that the presently claimed coding sequence differs from that of the '526 reference by insertion (creating a frame shift) and by deletion (re-establishing the frame) and therefore, it is not merely "an addition of a cytosine" in the sequence as compared to that of the reference cited by the Examiner. Therefore, withdrawal of this ground of rejection is requested.

In view of the amendments to the claims and the above remarks, it is believed that the claims clearly point out Applicants' patentable contribution and favorable reconsideration of the application is requested.

Respectfully submitted,
Muserlian, Lucas and Mercanti



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Enclosures